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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,190	10/31/2003	Barbara Grimpe	CWR-7779NP	1183

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EXAMINER	
LONG, SCOTT	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,190	GRIMPE ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *4, 7, 10-11, 14-16, 21-22, 35, 37-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,8,9,12,13,17-20,23-34 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1-54 are pending. Claims 4, 7, 10-11, 14-16, 21-22, 35, 37-54 were withdrawn by the examiner in the previous Office Action, as being drawn to non-elected inventions. Claims 1-3, 5-6, 8-9, 12-13, 17-20, 23-34 and 36 are under current examination.

Priority

This application claims benefit from provisional U.S. Application No. 60/423,082 filed 1 November 2002 and claims benefit from provisional U.S. Application No. 60/471,447 filed 16 May 2003. The instant application has been granted the benefit date, 1 November 2002 from the application 60/423,082.

Response to Arguments - Claim Rejections 35 USC § 112

Response to Arguments – 35 USC 112, second paragraph

Applicant's arguments, see page 2-5, filed 19 January 2007, with respect to claims 1-3, 5-6, 8-9, 12-13, 17-20, 23-34 and 36 have been fully considered and are found to be unpersuasive.

The applicant argues that claims 1, 17, 29, and 31 recited specific, active steps. The applicant also correctly points out that according to MPEP 2173.02, the

definiteness of claim language must be analyzed in light of (a) application disclosure, (b) prior art, (c) the understanding of one of ordinary skill in the art.

Particularly, the applicant argues that the applicant discloses both agents and methods for inhibiting expression of the primary proteoglycan. The examiner does not dispute that the specification discloses various agents. In fact, the examiner in his rejection of the examined claims under 35 USC 112, 2nd paragraph, notes that the claims recite "agents". This was not the reason that the examiner rejected the examined claims under this statute. Rather, the examiner's rejection is based on his analysis of the claims as not having any active steps. The primary purpose of the statue's requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under 35 U.S.C. 112, second paragraph (MPEP 2173). For example, a claim which read: "A process for using monoclonal antibodies of claim 4 to isolate and purify human fibroblast interferon." was held to be indefinite because it merely recites a use without any active, positive steps delimiting how this use is actually practiced (MPEP 2173.05(q)). The examiner maintains that the claims of the instant application are analogous to the example above. Reducing GAG content in the glial scar comprising inhibiting the expression of primary proteoglycans does not claim how it is done (i.e. – active steps or how it is actually practiced).

The applicant also argues that because the claims are written in "verb tense," that the claims, therefore, recite an active step. "Inhibiting" is not an active step. Merely using a verb having a participle, does not assist the public in understanding the boundaries of infringement, because it does not tell them the manner (active steps) of inhibiting.

Regarding the analysis of the claims according to MPEP 2173.02, the examiner has fully considered the applicant's arguments but finds them insufficient to overcome the rejection for the following reasons:

Application content: The examiner reiterates that he is not objecting to the claims because of any doubts about agents disclosed in the specification. In fact, the claims are drawn to methods, not products. The applicant claims that methods described in specification paragraphs 192-233 inform the artisan's understanding of claims 1, 17, 29, and 31. Paragraphs 192-194 describe gene therapy vectors capable of expressing various agents and brief recitation of in vivo method, which would be understandable to those of skill in the art of gene therapy. Paragraphs 195-209 describe technologies for production of recombinant proteins, which also would have been understandable to those of skill in the art of recombinant protein production. Paragraphs 210-215 describe concepts in combinatorial chemistry that could be used to generate new protein agents, based on modification of known agents suggested to inhibit expression of proteoglycans. Paragraphs 216-217 list other classes of potential inhibitors, including RNAi, antisense oligonucleotides, and small organic molecules. While listed, generically, these classes of molecules are either well characterized as

therapeutics or have had substantial research performed where their utility as a therapeutic is suggested. Paragraph 218 makes a general argument that biologically effective carriers for any type of pharmaceutical is desirable. Paragraphs 219-226 discuss a range of well studied gene therapy vectors, specifically focusing on viral gene delivery vectors, all well known in the art. Paragraphs 227-228 discuss non-viral gene therapy vectors, in a brief, but art understood manner. Overall the paragraphs discussed above discuss general classes of molecules or vectors for delivery of (gene therapy) agents. However, these paragraphs do not make up for the deficiency that claims 1 and 17 do not recite an active step, such as "administering an agent." Likewise there is no teaching that will overcome the deficiency that claims 29 and 31 do not describe any particular steps to screen the agents. Finally, paragraphs 229-233 describe direct administration of proteins to a cell and methods of transducing proteins into cells. In paragraph 230, particularly, the specification discusses administration of an antagonist of GAG chain initiation or elongation introduced into a cell. It is in these final paragraphs (pointed to by the applicant) that there seems to be more than mere generalities. Nevertheless, the independent claims 1, 17, 29, and 31 are not distinctly claimed and do not recited active steps and the portions of the specification indicated by the applicant as important to resolving these issues are found to be insufficient to overcome the rejection.

Prior art: There is no doubt in the examiner's mind that there is a need for reducing scar formation in regenerating neurons. The examiner also does not doubt the role of GAG-modifying proteoglycans in inhibiting neuronal regeneration. However,

these aspects of the prior art do not assist the general public in understanding the boundaries of the applicant's invention. In fact, as an argument supporting the metes and bounds of the claims, the applicant's arguments reinforce the examiner's conclusion that the claims are vague and indefinite. This argument is merely a suggestion that there is some involvement of the proteoglycans and inhibition of neuronal regeneration. This does not particularly address the rejection that the method is indistinctly claimed, has no active steps.

Skilled Artisan: Based on the above analysis, a skilled artisan would not know the metes and bounds of the claimed invention.

Therefore, the rejection of claims 1-3, 5-6, 8-9, 12-13, 17-20, 23-34 and 36 under 35 USC 112, second paragraph is hereby maintained.

Response to Arguments – ENABLEMENT (35 USC 112, first paragraph)

Applicant's arguments, see page 5-6, filed 19 January 2007, with respect to claims 1-3, 5-6, 8-9, 12-13, 17-20, 23-34 and 36 have been fully considered and are found to be unpersuasive.

The applicant has addressed the two aspects of the rejection of Claims 1-3, 5-6, 8-9, 12-13, 17-20, 23-34 and 36 under 35 USC 112, first paragraph (scope of enablement), as failing to enable (1) *in vivo* methods and (2) methods of administration other than topical and intrathecal administration.

The applicant accurately points out that the examiner, in his discussion of the working examples, discusses example 8, which describes *in vivo* administration ofXT-1 enzyme via intrathecal administration. Based on this example, the applicant attempts to overcome the rejection based on scope of enablement limited to *in vitro* methods. However, the examiner would like to reiterate (see Office Action, mailed 10/17/2006) that the mouse experiments were terminated before any clinical benefit was shown. The examiner also would like to reiterate that "because of the difficulties intrinsic to methods of neuroregeneration, the standard for enablement requires support for recovery of function. The examples in the instant application fail to whether there was clinical benefit to the animals treated." (page 6; Office Action, mailed 10/17/2006). For this reason, the examiner rejects this argument and maintains this portion of the scope of enablement rejection for claims 1, 17, 29 and 31 and their respective dependent claims.

Additionally, Example 8 discloses intrathecal administration. There are no other examples where any agent is administered to an animal. The specification discloses constructive embodiments for other forms of administration, but has not reduced to practice these other methods of administration. The intrathecal administration is a type of local administration that is akin to topical administration. For this reason, the examiner believed that delivery by topical administration was also enabled. However, since no other form of administration was exemplified, there is uncertainty as to the success of intramuscular or intravenous administration of agents in acting to permit neuronal regeneration.

It is noted that the applicant did not argue the unpredictableness of both treatments for spinal cord injury or for gene therapy, also included in the scope of enablement rejection.

Therefore, the rejection of claims 1-3, 5-6, 8-9, 12-13, 17-20, 23-34 and 36 under 35 USC 112, first paragraph (scope of enablement) is hereby maintained.

Response to Arguments - Claim Rejections 35 USC § 102

The Declaration filed on 1/19/2007 under 37 CFR 1.131 is sufficient to overcome the Grimpe et al. reference.

The Declaration filed on 1/19/2007 under 37 CFR 1.132 is sufficient to overcome the rejection of claims 1-2 and 5-6 based upon the Grimpe et al. reference under 35 U.S.C. 102(a).

Therefore, the examiner withdraws his rejection of claims 1-2 and 5-6, rejected under 35 U.S.C. 102(a) as being anticipated by Grimpe et al (The Journal of Neuroscience, April 15, 2002, 22(8):3144–3160).

Response to Arguments - Claim Rejections 35 USC § 103

The Declaration filed on 1/19/2007 under 37 CFR 1.131 is sufficient to overcome the Bradbury et al. reference.

Therefore, the examiner withdraws his rejection of claims 1-3, 5-6, 8-9, 12-13, 17-20, 23-34 and 36, rejected under 35 U.S.C. 103(a) as being unpatentable over

Bradbury et al. (Nature. (11 April 2002). 416: 636-640) in view of Santoro et al. (*PNAS. 1997; 94:* 4262-4266) and further in view of Götting et al. (J.Mol.Biol. 2000; 304: 517-528) and further in view of Marchetti (Frontiers in Bioscience 2 d. 88-125, March 1, 1997).

Claim Objections

Claim 1 is objected to because of the following informalities: The term "GAG" is an acronym that should be more clearly stated as, for example, "glycosaminoglycan (GAG)". Appropriate correction is required.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
Patent Examiner
Art Unit 1633